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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,023

Applicant(s)

BROWN ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 and 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1, 3, 5-10, and 26-33 have been amended. Claims 1-38 are pending. Claims 11-25 and 34-38 have been withdrawn as being drawn to a non-elected invention. Claims 1-10 and 26-33 are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-10 and 26-33 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the previous Office action.

Applicant's arguments filed December 12, 2005 have been fully considered but they are not persuasive.

Applicant contends that one of ordinary skill would have measured resistant starch levels by the McCleary method, it being the only AOAC-approved method for such a measurement and goes onto discuss the use of the McCleary method, along with the Muir method, in other references cited in the specification. However, Applicant suggests that one of ordinary skill would look to Brown et al (Food Austr., 1995), which was cited in the specification. This reference cites Prosky et al (JAOAC, 1988) as providing "the officially accepted method of the Association of Analytical Chemists" for detecting resistant starch. So it is not clear to the

Art Unit: 1623

examiner exactly what the Applicant's position is here: (1) One of ordinary skill would use any AOAC-approved method; (2) One of ordinary skill would use any method disclosed in a reference cited in the specification; (3) Something else.

Applicant notes that "the McCleary and Muir methods give results which are within the accepted experimental error and thus are considered to be the same." It is possible that one of ordinary skill would construe a particular RS percentage recited in a claim to have an assumed experimental error built in because of the lack of precision seen in the various methods used in the art—for example, "20%" is interpreted to be "20% \pm X%"—but this is not clear.

The examiner is not persuaded that at the time of the invention there was one accepted and standard method for the measurement of RS or that the instant specification clearly points to the use of any particular method. It is further noted that the Megazyme document, cited in the previous Office action discusses several methods used in the art. There is no mention of any particular industry standard. Finally, it is also noted that BENGS et al (WO 00/38537 – from Applicant's newly submitted IDS) uses the Englyst method to determine RS content. See Example 3.

Claim Rejections - 35 USC § 102

Claims 26-28 and 30-33 are again rejected under 35 U.S.C. 102(b) as being anticipated by BROWN et al (WO 96/08261) with McNAUGHT et al (WO 94/14342) to support inherency.

The claims have been amended to require that the RS is present in a proportion of at least 20% of the total starch content by weight. BROWN uses the McCleary method to determine that the RS% is 18.1, with no margin of error disclosed. In other measurements disclosed in Table 3,

Art Unit: 1623

the average margin of error is about 2%. It is noted that McNAUGHT uses the Muir method—deemed equivalent to McCleary by Applicant—to determine RS value of 20% ($\pm 1.8\%$) for what appears to be the same starch used in BROWN. Given the uncertainty of the metes and bounds of the range “at least 20%” as discussed above, it appears that the starch used in the BROWN composition is likely to fall in this range. The examiner does not agree that this amendment clearly avoids anticipation, as Applicant contends.

Claim Rejections - 35 USC § 103

Claims 6 and 29 are again rejected under 35 U.S.C. 103(a) as being unpatentable over KLOR et al (US 5,886,037) in view of WIBERT et al (US 5,776,887) and further in view of SEIB et al (US 5,855,946).

Claim 6 has been amended to require the daily carbohydrate intake comprises at least 15% RS. Claim 29 has been amended to require that RS is at least 20% of the total starch intake.

KLOR teaches a composition for the treatment of obesity and diabetes, as discussed in the previous Office action.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition according to the teaching of KLOR with a resistant starch, such as Novelose, because WIBERT had taught that it is a slowly absorbed carbohydrate and has utility in the preparation of food products. It would be further obvious to administer this composition for the treatment of obesity with a reasonable expectation of success, because KLOR had taught this utility. A product prepared according to KLOR and administered in the amount of about 2000 kcal/day, would provide amylase-resistant starch and unsaturated fat in the

Art Unit: 1623

required amounts. It would be within the scope of the artisan to optimize the amount of RS and unsaturated fat within the ranges disclosed in the art, for the purpose of treating obesity.

Applicant's arguments filed December 12, 2005 have been fully considered but they are not persuasive.

Applicant appears concerned about the terminology used in the KLOR abstract stating "polyunsaturated chain fatty acids caprylic and capric acid" whereas these species are actually saturated acids. The examiner agrees with this assessment. However, the discussion in col 4 and the itemized fat species in Table 2 make it clear as to the types of fats and what the reference considers "polyunsaturated" vs. "saturated" fat. Applicant further states that the reference emphasizes the benefits of a composition having 55-95% saturated fat. The examiner agrees but does not see how that presents any particular conflict with the instant claims. The reference teaches a range of 55-95% saturated fat, while the instant claims allow for a range of 0-90%.

Applicant contends that KLOR fails to teach the use of RS. The examiner agrees and stated as much in the previous Office action. It was WIBERT that provided the teaching for using RS. However, KLOR specifically suggests using (1) starch as the carbohydrate component; and (2) a carbohydrate that generates a relatively small rise in plasma lipid or insulin levels.

Applicant further argues that there is no teaching in KLOR that the replacement to Applicant's method for regulating carbohydrate and fat metabolism. However, the claims are drawn to a method of treating obesity, which is taught.

Applicant discusses all the types of fats disclosed in WIBERT and concludes that the reference "gives no indication with regard to the types of fats that should be consumed and would not have motivated on to replace the saturated fat in KLOR with unsaturated fat." First of

Art Unit: 1623

all, the type of fat disclosed by WIBERT is not germane to this rejection. This reference was used solely for the teaching regarding the fact that Novelose® is a slowly absorbed carbohydrate with a low glycemic index, and that is known to be useful in the preparation of food products. With regard to replacing saturated fat with unsaturated fat, there is no additional teaching necessary because KLOR provides for the use of those fats in the range required by the claims.

Applicant further contends that one of ordinary skill would not combine the teachings of KLOR and WIBERT to arrive at the composition of the invention because the two references have a different focus.

Applicant states that carbohydrates are “optional” for KLOR compositions, which have very large amounts of saturated fat. While carbohydrates may not be required in the independent claim, the reference specifically states that “complete foods are preferred” with a preferred composition of 28-38 wt% fat; 30-50 wt% carbohydrate; and 15-30 wt% protein. See paragraph bridging col 4-5. As previously noted, the reference specifically exemplifies a composition having the required amount of unsaturated fat.

With respect to WIBERT, Applicant contends that this reference is directed to a composition comprising mostly carbohydrates and that it recommends no particular amount of RS starch or motivation to choose unsaturated fat. Again, the particular compositions are not relevant to the rejection. This reference was used to teach the suitability for using RS in the KLOR composition. KLOR provides all the necessary amounts of fat and carbohydrate.

Finally, Applicant notes that SEIB does not teach one to alter the composition of WIBERT to arrive at the instant invention. The examiner agrees, but that was not the reason for

Art Unit: 1623

using SEIB. This reference was used to determine the amount of amylase resistant starch in the product Novelose®.

Claims 1-5, 7-10, 26-28 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIBERT et al (US 5,776,887) in view of SEIB et al (US 5,855,946).

WIBERT teaches the preparation of compositions for the use by diabetics and those susceptible to diabetes for controlling blood glucose levels. These compositions comprise slowly absorbed carbohydrates, such as Novelose® (33% RS, as per SEIB) with this carbohydrate being exemplified in several of the embodiments. See col 6, lines 3-17; Example 4; and reference claim 14. The composition of Example 4 comprises about 2.2 g of RS, or 22% of the total carbohydrate content. The fat component appears to be essentially limited to unsaturated fat.

It would be have been obvious to one having ordinary skill in the art at the time the invention was made to administer a composition, such as the one exemplified in example 4, to a diabetic or pre-diabetic to control blood glucose levels. In the course of administering this composition in an amount needed to attain adequate energy requirements, a subject would necessarily ingest the particular amounts of RS and unsaturated fat required by claims 26-28 and 31-33. It is noted that none of these claims require any particular patient population. In administering the composition as directed by the reference, the methods would be accomplished.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1623

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier

Leigh C. Maier
Patent Examiner
March 3, 2006